



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0045]

Draft Guidance for Industry on Abuse-Deterrent Opioids--Evaluation and Labeling; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Abuse-Deterrent Opioids--Evaluation and Labeling.” The draft guidance describes how abuse-deterrent properties of opioid analgesic products should be studied and evaluated, and what claims regarding such properties may be suitable for inclusion in labeling. In addition to general input on this draft guidance, FDA is seeking input on the research topics outlined in the final section of the draft guidance. FDA also intends to hold a public meeting to solicit additional input from affected stakeholders on the draft guidance.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the

SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>.

Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Matthew Sullivan,
Center for Drug Evaluation and Research (HFD-170),
Food and Drug Administration,
10903 New Hampshire Ave.,
Bldg. 22, rm. 3160,
Silver Spring, MD 20993,
301-796-1245,
matthew.sullivan@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Abuse-Deterrent Opioids--Evaluation and Labeling.” Prescription opioid analgesics are an important component of modern pain management, but abuse and misuse of these products remains a serious and growing public health problem. One important effort in reducing abuse and misuse is the development of opioid analgesics specially formulated to deter abuse. FDA considers development of abuse-deterrent opioid analgesics to be a public health priority and is encouraging their development.

This draft guidance is intended to provide industry with a framework for evaluating and labeling abuse-deterrent opioid products. The draft guidance discusses how the potentially abuse-deterrent properties of an opioid analgesic formulated to deter abuse should be studied, specifically addressing in vitro studies, pharmacokinetic studies, human abuse potential studies, and postmarket studies. The draft guidance also describes the types of information and claims that may be suitable for inclusion in labeling.

Providing a clear framework for the evaluation and labeling of the abuse-deterrent properties of opioid analgesics intended to deter abuse should help to incentivize the development of safer, less abusable opioid analgesics, and should also facilitate the dissemination of fair and accurate information regarding such products. FDA also expects that the publication of this draft guidance will stimulate a productive discussion among FDA, industry, and other stakeholders concerning the appropriate development, evaluation, and labeling of these products. In the final section of the draft guidance, FDA also lists several areas where additional scientific research and analysis would be especially helpful.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). FDA also intends to hold a public meeting to solicit additional input from affected stakeholders on the draft guidance. The guidance, when finalized, will represent the Agency's current thinking on evaluation and labeling of abuse-deterrent opioids. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: January 8, 2013.

Leslie Kux,

Assistant Commissioner for Policy.